

Pharmacy Student Rotation in the Food and Drug Administration's Center for Drug Evaluation and Research (CDER), Division of Drug Information

Goals: The purpose of this rotation is to familiarize the student with the role of the Food and Drug Administration (FDA) in the drug development, review, and post-marketing phases, as well as offer experience in providing drug information to consumers, health care professionals, and industry.

I. Learning Objectives: Upon completion of this rotation the student will be able to:

- A. Describe the development of a new drug from laboratory to commercial distribution of the product and the FDA's role in that process.
- B. Distinguish between the three phases of clinical trials in the drug development process.
- C. Discuss ways the FDA makes new drugs available to patients prior to approval.
- D. Outline the post-marketing surveillance mechanisms the FDA uses to assure drugs remain safe and effective for the American people.
- E. Utilize drug information and FDA resources such as Medline, Micromedex, and the Federal Register, and become familiar with what type of information is posted on the FDA's web page and CDER's Internet.
- F. Answer questions /become familiar with the laws, regulations, and guidance documents governing drugs.
- G. Respond to inquires regarding FDA approved products.

II. Student Requirements: The student will be exposed to a variety of questions regarding all aspects of pharmaceuticals and the pharmaceutical industry. The program will focus on familiarizing the student with the type of information collected and what is releasable from the FDA. To meet these objectives the student will be expected to:

- A. Respond to drug information requests from consumers regarding general drug information, adverse effects, and potential drug interactions.
- B. Return all phone calls the same day.
- C. Answer at least 10 emails per day.
- D. Be familiar with current drug news in the media.
- E. Give a presentation or conduct a project assigned by preceptor.
- F. Attend student rotations within the Office of the Commissioner and the Center for Drug Evaluation and Research.
- G. Fulfill required hours.
- H. Document all daily and monthly phone calls and emails.